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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,854	LI, CHIANG J.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2006 and 12 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,9-17,35,38,39,43-51,53 and 55-74* is/are pending in the application.

4a) Of the above claim(s) *55-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-5,9-17,35,38-39,43-51,53,73-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 55-74 are presented for examination.

Applicant's Amendment filed May 17, 2006 and the replacement drawings filed June 12, 2006 in response to the Notice of Non-Responsive Amendment dated May 31, 2006, have each been received and entered into the application. Accordingly, Figures 12 and 13 have been replaced.

Claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 55-74 remain pending. Claims 55-72 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b), claims 2-3, 6-8, 18-34, 36-37, 40-42, 52 and 54 have been cancelled, claims 1, 4, 5, 9, 11-15, 17, 35, 38-39, 43, 45-49, 51 and 53 are amended and claims 73-74 are newly added.

Applicant's arguments, filed May 17, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

(New Ground of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 9-17, 35, 38-39, 43-51 and 73-74 are rejected under 35 U.S.C. 112, first

paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. "If new matter is added to the claims, the Examiner should reject the claims under 35 U.S.C. 112, first paragraph-written description requirement. *In re Rasmussen.* 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." (See MPEP §2163.06(I)).

An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Present claims 1 and 35 are amended and are now drawn to a method of treating prostate, colon, breast, pancreatic or lung cancer comprising the administration of a G1 and/or S phase checkpoint activator to a subject in need thereof, wherein the checkpoint activator is administered "in a dosage effective manner, wherein said dosage is determined by measuring the unscheduled expression of a member of the E2F family of transcription factors, selected from the group consisting of E2F-1, E2F-2 and E2F-3, and wherein said dosage is sufficient to selectively activate a checkpoint in cancerous cells, but not affect the cytotoxicity or viability of non-cancerous cells", and further wherein the checkpoint activator is not beta-lapachone.

In particular, the specification as originally filed fails to provide written support for now claiming the determination of a dosage of checkpoint activator via measuring the "unscheduled expression" of an E2F transcription factor.

Respecting the limitation of "wherein said dosage is determined by measuring the

unscheduled expression of a member of the E2F family of transcription factors, selected from the group consisting of E2F-1, E2F-2 and E2F-3", Applicant identified portions of the specification that allegedly provide written support to now claim the step of determining the appropriate dosage amount of the checkpoint activator by measuring E2F transcription levels. However, such disclosure does not support the actual step of determining the dosage of the checkpoint activator. Rather, the disclosure identified by Applicant merely supports a method of screening and identifying compounds effective as checkpoint activators by measuring the degree or extent of elevation of an E2F transcription protein. For example:

> "In another embodiment, the present invention relates to a method for screening for a cell cycle checkpoint activation modulator by contacting a cancer cell with a candidate compound, and measuring the degree (or extent) of elevation of a member of the E2F family of transcription factors (including but not limited to E2F-1, E2F-2 or E2F-3), if present, where an increase in E2F in the presence of the compound, as compared to the absence of the compound, indicates that the compound is an inducer of apoptosis." (page 8, lines 3-8)

However, such disclosure does not adequately support Applicant's claims now drawn to the determination of an effective dosage of the checkpoint activator by measuring the expression of an E2F transcription factor. It is clear from the above passage that Applicant contemplates screening possible compounds for efficacy in modulating the expression of E2F transcription factor(s) as a measure of the potency of the compound as a checkpoint activator, but Applicant fails to disclose, either expressly or implicitly, an embodiment wherein the appropriate dosage of the checkpoint activator is determined via measuring the expression of an E2F transcription factor. In fact, the generic disclosure of "administering in a dosage effective manner" does not encompass or provide sufficient written description to now claim a particular method of how to determine the most effective dose to be administered.

Considering the teachings, provided in the specification as originally filed, Applicant has

failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concept of measuring the expression of an E2F transcription factors in order to determine the dosage of checkpoint activator to be administered (please see, for example, present claims 1 and 35 and the dependent claims therefrom).

Accordingly, for these reasons, claims 1, 4-5, 9-17, 35, 38-39, 43-51 and 73-74 are properly rejected under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 73-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of a G1 and/or S phase checkpoint activator selected from 3,4-dihydro-4,4-dimethyl-2H-naptho[1,2-b]thiopyran-5,6-dione; 3,4-dihydro-2,2-dimethyl-2H-naptho[1,2-b]thiopyran-5,6-dione; 3,4-dihydro-2,2-dimethyl-3-(3-methyl-2-butenyl)-2H-naptho[1,2-b]pyran-5,6-dione; or beta-lapachone, for the treatment of prostate, colon, breast, pancreatic or lung cancer, does not reasonably provide enablement for the administration of a dose that selectively activates a checkpoint in cancerous cells but does not affect the cytotoxicity or viability of non-cancerous

cells, for the reasons set forth at pages 5-11 of the previous Office Action dated January 17 2006, of which said reasons are herein incorporated by reference.

Applicant traverses the rejection on the grounds that the claims as amended now require that the checkpoint activator is administered in a dosage effective manner where the dosage is determined by measuring the unscheduled expression of a member of the E2F family of transcription factors. Applicant submits that the present invention provides compounds and methods that selectively treat cancer cells without affecting the non-cancerous cells and that one of ordinary skill in the art would be able to readily determine the effective therapeutic dosage for a particular subject dependent on, e.g., sex, height, weight, etc., without undue experimentation.

Applicant's traversal and remarks have been carefully considered in their entirety, but fail to be persuasive.

In particular, it is noted that although Applicant has amended the claims to now read upon an additional step of determining the appropriate dosage of the checkpoint activating compound by measuring the unscheduled expression of a member of the E2F family of transcription factors, the specification as originally filed, either in the disclosure itself or the examples or accompanying figures, does not contain: (1) adequate written description of such an embodiment or (2) a protocol as to how one of ordinary skill in the art would go about measuring the level of E2F transcription factors and how the skilled artisan would translate such a level of E2F transcription factors into a particular dosage amount of checkpoint activator while preserving the viability of non-cancerous cells (i.e., protecting non-cancerous cells from the cytotoxic effects of the checkpoint activator). Given the state of the art at the time of the present invention, which recognized the complex nature of treating cancer in general and also the toxic

nature of chemotherapeutic cancer treatments not only to the tumor itself but also to the normal cells of the body, thus, resulting in numerous adverse side effects, one of ordinary skill in the art would have had reason to doubt Applicant's allegation that the dosage(s) of checkpoint activator sufficient to selectively activate a checkpoint in cancer cells and thereby induce apoptosis or inhibit cellular proliferation would not have any effect whatsoever on non-cancerous cells in the absence of any direction by the Applicant as to how such an objective would have been achieved.

Applicant's attention is directed to *In re Marzocchi*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

The state of the art at the time of the invention clearly dictates against the allegation that it would have been within the routine skill of the artisan and would not have required undue experimentation to determine the dosage amount of checkpoint activator that would selectively affect only tumor cells and with no cytotoxic effect on non-cancerous cells. Each and every chemotherapeutic regimen available in the art is replete with toxic effects not only on the offending tumor, but also on the body as a whole, due precisely to the fact that the cytotoxic

effects of the chemotherapeutic agents cannot be isolated or localized solely to the tumorigenic tissues and cells that are intended to be treated. In other words, Applicant's claim that the dosage amounts of the checkpoint activator determined by this measurement of E2F transcription factor expression are selective for cancerous cells and have no cytotoxic effect on non-cancerous cells (i.e., do not affect the viability of non-cancerous cells) would have been an outcome not reasonably expected by one of ordinary skill in the art at the time of the invention.

For these reasons, Applicant's assertion that the skilled artisan could readily determine the dosage amounts during the course of routine experimentation is directly contrary to the state of the art at the time of the invention. In the absence of any protocol as to how to actually measure the E2F transcription factor expression, how to translate such a measurement into an appropriate dosage amount and what criteria would be used to determine those dosage amounts that selectively activate checkpoints in cancerous cells, but have no cytotoxic effect in non-cancerous cells, the specification is viewed as lacking an enabling disclosure of the manner and process of this embodiment of the invention.

Furthermore, Applicant's allegation that one of ordinary skill in the art would readily be able to determine the effective therapeutic dosage for a particular subject dependent on particular conditions without undue experimentation does not rebut the presumption of unpredictability in the art. Applicant has failed to provide any concrete evidence or persuasive argument other than Counsel's own assertion that such would a determination would be within the skill of the artisan. Please reference MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965)."

For these reasons, and those previously made of record at pages 5-11 of the previous Office Action dated January 17 2006, rejection of claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 73-74 is proper and is **maintained**.

Claim Rejections - 35 USC § 112, Second Paragraph (New Ground of Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-5, 9-17, 35, 38-39, 43-51 and 73-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, Applicant fails to clearly delineate on the record what is meant by the phrase "unscheduled expression of a member of the E2F family of transcription factors" in the accompanying disclosure. In light of such, the skilled artisan would not have been reasonably apprised of the metes and bounds of the claimed subject matter for which Applicant is seeking protection. For example, it is not clear as to what is "unscheduled" about the expression, how one would recognize whether the expression was "unscheduled" and how said "unscheduled expression" is different than "scheduled expression".

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 73-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the limitation "but not affect the cytotoxicity or viability of non-cancerous cells" in present claims 1 and 35 does not clearly delineate on the record what Applicant intends by "does not affect the cytotoxicity...of non-cancerous cells". "Cytotoxicity" itself is not a state of being; rather, it is the action of, relating to, or producing a cytotoxic effect on a cell. In other words, it is unclear whether Applicant intends to claim that the dosage is sufficient to selectively activate a checkpoint in cancerous cells but does not have a cytotoxic effect on non-cancerous cells and, thus, does not affect their viability, or some other circumstance that is not readily apparent from the claim(s) as presently written.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

Claim Rejections - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pardee et al. (U.S. Patent No. 6,875,745) in view of Dyson ("The

Regulation of E2F by pRB-Family Proteins", *Genes and Development*, 12:2245-2262; 1998), each previously made of record.

Pardee et al. teach a method for treating a mammalian tumor by administering a G1 and/or S phase drug, preferably the topoisomerase I inhibitor beta-lapachone or a derivative or analog of beta-lapachone (i.e., orthonapthoquinones; see present claims 73-74), in combination with a G2/M phase drug, preferably taxane or a derivative or analog of taxane (see abstract and col.2, lines 45-65). The reference states that "molecular changes underlying cell cycle delay at multiple checkpoints, for example G1 and/or S phase and G2/M phase, can for example result in synergistic induction of apoptosis in malignant cells" (col.5, lines 21-26). The combination reduces tumor burden load and/or regresses tumor growth, with the specific cancers to be treated including breast, ovarian, prostate, lung, colon, and melanoma (col.7, lines 59-65; Figs. 6 and 7; Examples 1-4; Table 2 at col.17).

The reference teaches that the compounds can be administered by any means known in the art, including parenteral, intravenous, oral, and topical, thus, meeting the limitations of instant claims 11-14 (col.7, line 66-col.8, line 3). The reference also describes pharmaceutically acceptable dosage formulations (col.12, lines 31-51).

The reference teaches administration of the cell cycle checkpoint activation drug in combination with a chemotherapeutic agent. The preferred G2/M phase checkpoint targeting drugs to be used in combination with the G1/S phase beta-lapachone derivatives include microtubule targeting drugs (for example, taxol, docetaxel, vincristine, vinblastine, nocodazole, epothilones, navelbine, and methotrexate) and topoisomerase poisons (for example, teniposide,

etoposide, adriamycin, camptothecin, daunorubicin, dactinomycin, mitroxantrine, amsacrine, epirubicin, and idarubicin). Please see col.4, line 5-col.7, line 62 and Table 1.

The reference teaches the beta-lapachone derivative 3,4-dihydro-2,2-dimethyl-3-(3-methyl-2-butenyl)-2H-naptho[1,2-b]pyran-5,6-dione of instant claim 9: Formula V where R7 is an alkenyl (see col.11).

In view of the fact that Pardee et al. expressly teaches an identical checkpoint activating compound to that presently claimed, the specific physical and functional properties of the compound (i.e., a molecular weight of less than 5 kD or that the compound does not damage DNA and does not stabilize microtubules) are inherent to the compound and are, thus, necessarily present in the reference.

The differences between the Pardee et al. reference and the presently claimed subject matter lie in that the reference fails to expressly teach the step of determining the dosage amount of the checkpoint activating compound by measuring the expression of a member of the E2F family of transcription factors, i.e., E2F-1, E2F-2 or E2F-3, and determining the dosage that is sufficient to selectively activate a checkpoint in cancerous cells, but does not exert a cytotoxic effect or affect the viability of non-cancerous cells.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Dyson teaches that E2F transcription proteins play an important role in cell proliferation and differentiation. Dyson states, "E2F is regulated in a cell cycle-dependent manner and fluctuations in E2F activity enable programs of gene expression to be coupled closely with cell

cycle position...Further studies have shown that activation of E2F-dependent transcription promotes cell cycle progression and S-phase entry." (see paragraphs 1 and 2 of column 2, page 2245)

In light of such, it would have been *prima facie* obvious to one of ordinary skill in the art to monitor the levels of E2F transcription proteins in order to determine cell cycle position and maximize the cytotoxic effects of the checkpoint activating beta-lapachone derivative compound by administering a dosage amount effective to counteract cellular proliferation once E2F activation was detected, indicating that the cells had progressed to S-phase. Such a person would have been motivated to do so because the checkpoint activating beta-lapachone derivative compounds of Pardee et al. were selective for G1 and/or S phase and, thus, would have exerted the greatest apoptotic effect and inhibitory effect on cellular proliferation when targeted for administration at S-phase entry, which was known to correlate specifically to activation and expression of E2F transcription proteins. Additionally, one of ordinary skill in the art would have further been motivated to determine the dosage amount that was effective to exert a cytotoxic effect on tumor cells with minimum toxic effects on non-cancerous cells in order to reduce the incidence of toxicity in the subject receiving such a treatment.

Double Patenting

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 73-74 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims contained within U.S. Patent Application Nos. 10/866,751; 10/887,009; 10/995,565; 11/068,459; 11069,637; and 11/201,097, each already of record, for the reasons of record set forth at pages 3-5 of the previous Office Action dated January 17, 2006, of which said reasons are herein incorporated by reference.

Cancellation of claims 2-3, 6-8, 18-34, 36-37, 40-42, 52 and 54 renders the present rejections **moot** as applied to such claims.

Newly added claims 73-74 are properly included in the present rejections because the claimed species of beta-lapachone derivative are orthonapthoquinones.

The rejection over U.S. Patent Application No. 10/007,352 is **withdrawn** since this application has been abandoned and is no longer currently pending before the Office.

Applicant states that they will review these pending application and will consider filing a Terminal Disclaimer upon notice of allowable subject matter in these applications or in the instant application.

In the absence of any remarks to the contrary or any Terminal Disclaimers, and further in light of the fact that allowable subject matter has not yet been identified in this or any copending application, the present provisional rejections remain proper for the reasons of record and are hereby **maintained**.

Conclusion

Rejection of claims 1, 4-5, 9-17, 35, 38-39, 43-51, 53 and 73-74 remains proper and is **maintained**.

Claims 55-72 remain **withdrawn** from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

August 24, 2006

Ardin H. Marschel 8/24/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER